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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,440	03/26/2004	Ikuo Matsui	13558-002002	8967

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,440	MATSUI ET AL.	
	Examiner	Art Unit	
	Yong D. Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SOD.

DETAILED ACTION

This application is a divisional of 09/967,645, which is now abandoned.

The amendment filed on June 3, 2005, canceling claims 36-37 and amending claim 38, has been entered.

Claim 38 is pending and is under consideration.

Information Disclosure Statement

The information disclosure statement filed on June 3, 2005 fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement filed on June 3, 2005 fails to comply with 37 CFR 1.97(c) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

Response to Arguments

Applicant's amendment and arguments filed on June 3, 2005, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is drawn to a method of obtaining an amino acid by contacting an enzyme with another amino acid. Therefore, even if the enzyme does not catalyze any reaction, the end product is still an amino acid already present in the reaction. Therefore, the claim makes no scientific sense and the metes and bounds of the claim is not clear to the Examiner.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of obtaining an glutamic acid using a polypeptide comprising the amino acid sequence of SEQ ID NO:1 and 2-ketoglutaric acid as its substrate, does not reasonably provide enablement for a method of obtaining any or all amino acid using SEQ ID NO:1. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claim 38 is drawn to a method of obtaining any amino acid by using an aminotransferase of SEQ ID NO:1. Therefore, these claims are drawn to a method of obtaining any amino acids even though the specification is limited to the teaching and making of only glutamic acid.

It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides. The specification is limited to teaching the use of polypeptide comprising the amino acid sequence of SEQ ID NO:1 to make glutamic acids but provides no guidance with regard to the making of any or all amino acids. In view of the great breadth of the claim, amount of experimentation required to make the claimed amino acids, the lack of guidance, working examples, and unpredictability of the art in making any or all amino acids, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by the claim.

The specification does not support the broad scope of the claim which encompasses a method of making any or all amino acids using the aminotransferase of SEQ ID NO:1 because the specification does not establish: (A) a rational and predictable scheme for making any amino acid using the above aminotransferase; and (B) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including method of using SEQ ID NO:1 to make any or all amino acids. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making any or all amino acids using the aminotransferase of SEQ ID NO:2 and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office Action, applicants have traversed the above rejection but since applicants have amended claim 38 to recite that the enzyme used in the method only comprises the amino acid sequence of SEQ ID NO:1, no undue experimentation would have been required to practice the claimed invention. Examiner respectfully disagrees. The claims are drawn to a method of making any amino acids using the aminotransferase of SEQ ID NO:2. The specification only teaches using SEQ ID NO:2 to make glutamic acid. It would require undue experimentation of the skilled

artisan to make and use the claimed polypeptides. The specification provides no guidance with regard to the making of any or all amino acids. In view of the great breadth of the claim, amount of experimentation required to make the claimed amino acids, the lack of guidance, working examples, and unpredictability of the art in making any or all amino acids, the claimed invention would require undue experimentation.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38 is rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kawarabayasi et al. and Warren et al.

Claim 38 is drawn to a method of obtaining an amino acid by contacting an aminotransferase having the amino acid sequence of SEQ ID NO:1 with an aromatic amino acid and an α-keto acid.

Kawarabayasi et al. (form PTO 892) teaches an aminotransferase that is 100% identical to SEQ ID NO:1 of the instant invention (pages 56-59 and 65 and see Sequence Alignment – cited on previous form PTO-892). The aminotransferase of Kawarabayasi et al. is from a thermophilic bacterium (abstract). The aminotransferase of Kawarabayasi et al. inherently possesses the same material structure and functional characteristics as the aminotransferase of claim 38 since the aminotransferase of Kawarabayasi et al. and the aminotransferase of the instant invention are the same enzyme. Further, this enzyme's inherent function is to transfer amino groups. From the teaching of Kawarabayasi et al., one having ordinary skill in the art would have recognized to use the enzyme of Kawarabayasi et al. to make amino acids.

In the alternative, Warren et al. (WO 97/29187 - form PTO-892) teaches a method of obtaining an amino acid by contacting an aminotransferase with an aromatic amino acid and an α-keto acid acid (pages 1-2).

Therefore, combining the teachings Kawarabayasi et al. with that of Warren et al., it would have been obvious to one having ordinary skill in the art to use the aminotransferase of Kawarabayasi et al. to make amino acids using the method of Warrant et al. One having ordinary skill in the art would have been motivated to use the aminotransferase of Kawarabayasi et al. since enzymes isolated from thermophilic organisms have high thermostability and higher optimum temperature, which are advantageous in making products in an industrial scale. One of ordinary skill in the art would have had a reasonable expectation of success since Kawarabayasi et al. teaches an aminotransferase having an amino acid sequence that is 100% identical to the instant aminotransferase and Warren et al. successfully teach a method of obtaining an amino acid by contacting an amino acid and an α-keto acid with an aminotransferase.

Therefore, the above references render claim 38 *prima facie* obvious to one of ordinary skill in the art.

A new rejection of claim 38 was warranted in view of amendment of claim 38.

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652

Manjunath Rao
Primary Patent Examiner 1652